

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC

FSIS DIRECTIVE	7700.1	2-22-00
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IRRADIATION OF MEAT AND POULTRY PRODUCTS

I. PURPOSE

This directive provides inspection program personnel with information and instructions regarding the irradiation of meat and poultry products in official establishments.

II. [RESERVED]

III. [RESERVED]

IV. REFERENCES

9 CFR 317, 318, and 381

21 CFR 179.26

FSIS Directives 5000.1 and 5400.5

V. BACKGROUND

On December 23, 1999, the Agency published the final rule, Irradiation of Meat Food Products, 64 FR 72150. This rule permits the use of ionizing radiation for treating refrigerated or frozen/uncooked meat, meat byproducts, and certain other meat food products to reduce levels of food borne pathogens and to extend the shelf life of these products. The final rule also revised the regulations governing the irradiation of poultry products so that they are more consistent with the regulations for the irradiation of meat food products.

Irradiation is a process of exposing food to high levels of radiant energy. Irradiation penetrates deeply into food, killing microorganisms without raising the temperature of the food significantly. Scientific data indicate that ionizing radiation can significantly reduce levels of many of the pathogenic microorganisms of concern in meat food products, including *Salmonella*; *Escherichia coli* O157:H7; *Staphylococcus aureus*; *Listeria monocytogenes*;

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Campylobacter jejuni; and the protozoan parasite *Toxoplasma gondi*. Irradiation is just one of the many treatments that can be used with a HACCP system to reduce the level of pathogens in meat and poultry.

If official establishments choose to irradiate meat food and poultry products, they must do so in accordance with the Hazard Analysis and Critical Control Point (HACCP) system requirements in part 417 of the regulation and the regulations specific to irradiation in section 424. Any facility that irradiates meat food and poultry products is designated as an official establishment and therefore is not permitted to operate under another establishment's HACCP plan. Each official establishment must develop and implement its own plan. Establishments using irradiation must, of course, meet other applicable FSIS requirements, such as adhering to the zero tolerance requirements for visible fecal matter on meat and poultry carcasses.

Meat and poultry establishments using irradiation also must meet other Federal regulatory safety requirements. The Nuclear Regulatory Commission (NRC) has regulations applicable to the possession and use of radioactive materials as well as other safety requirements. The Food and Drug Administration has use requirements, and States enforce the Occupational Safety and Health Administration (OSHA) regulations for possession.

VI. GENERAL REQUIREMENTS

1. What are the regulatory requirements for irradiation use?

Section 424.22 (c) (1) states, "General requirements. Meat food and poultry products may be treated to reduce foodborne pathogens and to extend product shelf-life by the use of sources of ionizing radiation as identified in 21 CFR 179.26(a). Official establishments must irradiate meat food and poultry products in accordance with 21 CFR 179.26(b), the Hazard Analysis and Critical Control Point (HACCP) system requirements in part 417 of this chapter, and the provisions of this section."

2. What can I expect an establishment to have in its HACCP plan?

In meeting the requirements of 9 CFR 417.2, all establishments irradiating product will address the use of irradiation in their hazard analysis. If an establishment determines that irradiation will be used to prevent a food safety hazard reasonably likely to occur (i.e., they are using it as an anti-microbial to eliminate or reduce the level of pathogenic organisms), the establishment will need to modify its HACCP plan. These establishments would likely designate irradiation as a CCP and possibly have other CCPs that would address such practices as holding the product at a certain temperature. Critical limits could

be the absorbed dosage, as measured by dosimetry, temperature of the product, or other processing parameters that reflect the efficacy of irradiation. Because products may be irradiated off-site, some establishments may not complete the final pre-shipment review until receiving notice from the irradiation facility that the procedure is complete. In such cases, both the establishment from which the product originated and the irradiator probably would have CCPs for irradiation.

Note: Inspection program personnel should not collect any samples from product to be irradiated (e.g., sampling for Salmonella performance standards) if the establishment's HACCP plan states that the product will be irradiated off-site. Inspection program personnel should only collect samples after the irradiation treatment.

If an establishment claims that irradiation is being used solely for the purpose of extending shelf life, it is conceivable, although highly unlikely, that the establishment could disregard any amount of pathogen reduction achieved by the irradiation and therefore not list irradiation as a CCP in its HACCP plan. These establishments should have an explanation in their hazard analysis as to why irradiation is not addressed in their HACCP system in order to meet the requirements in 424.22(c)(1). These establishments still must meet the regulatory requirements for dosimetry, documentation, and labeling.

3. How do I verify compliance?

Under the appropriate 03 ISP code, review the establishment's hazard analysis and HACCP plan to verify that documentation, as required in section 417.5(a) of the HACCP regulations, is present.

For irradiation incorporated into HACCP under the appropriate 03 ISP code or for irradiation not incorporated into HACCP under ISP code 04B04, on an ongoing basis, you may directly observe procedures related to irradiation or recordkeeping.

VII. DOSIMETRY

1. What are the regulatory requirements for dosimetry?

Section 424.22 (c)(2) states:

“(2) Dosimetry. Official establishments that irradiate meat food and poultry products must have the following procedures in place:

(i) Laboratory operation procedures for determining the absorbed dose value from the dosimeter.

(ii) Calibration criteria for verifying the accuracy and consistency of any means of measurement (e.g., time clocks and weight scales).

(iii) Calibration and accountability criteria for verifying the traceability and accuracy of dosimeters for the intended purpose, and the verification of calibration at least every 12 months. To confirm traceability, establishments must relate, through documentation, the end point measurement of a dosimeter to recognized standards.

(iv) Procedures for ensuring that the product unit is dose mapped to identify the regions of minimum and maximum absorbed dose and such regions are consistent from one product unit to another of like product.

(v) Procedures for accounting for the total absorbed dose received by the product unit (e.g., partial applications of the absorbed dose within one product lot).

(vi) Procedures for verifying routine dosimetry, i.e., assuring each production lot receives the total absorbed dose. Establishments may either position one dosimeter at the regions of minimum and maximum absorbed dose (or at one region verified to represent such) on at least the first, middle, and last product unit in each production lot or use statistically based validation and dose mapping to determine the number and placement of dosimeters in each production lot.

(vii) Procedures for verifying the relationship of absorbed dose as measured by the dosimeter to time exposure of the product unit to the radiation source.

(viii) Procedures for verifying the integrity of the radiation source and processing procedure. Aside from expected and verified radiation source activity decay for radionuclide sources, the radiation source of processing procedure must not be altered, modified, replenished, or adjusted without repeating dose mapping of product units to redefine the regions of minimum and maximum absorbed dose.”

2. How do I verify compliance?

For irradiation incorporated into HACCP under the appropriate 03 ISP code or for irradiation not incorporated into HACCP under ISP code 04B04,

Observe laboratory operation procedures used to determine the dose value from the dosimeter.

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Ask about the calibration criteria used for verifying the accuracy and consistency of any means of measurement.

Review documentation that addresses the end point measurement of a dosimeter.

Observe dose mapping procedures.

Check how the establishment accounts for the total absorbed dose. If product received higher than the maximum dosage allowed, the product is considered to be adulterated. (Note: The product cannot be brought into compliance. The product

must be condemned.) Verify that the establishment has taken appropriate actions for product disposition.

Ask how the establishment determined the number and placement of dosimeters.

Observe how the establishment determines the relationship of the absorbed dose as measured by the dosimeter to time exposure of the product unit to the radiation source.

Check that the establishment makes the necessary adjustments to dosimetry procedures if the radiation source is altered, modified, replenished, or adjusted.

VIII. DOCUMENTATION

1. What are the regulatory requirements for documentation?

Section 424.22 (c)(3) states:

“(3) Documentation. Official establishments that irradiate meat food or poultry products must have the following documentation on premises, available to FSIS:

(i) Documentation that the irradiation facility is licensed or possesses gamma radiation sources registered with the Nuclear Regulatory Commission (NRC) or the appropriate State government acting under authority granted by the NRC.

(ii) Documentation that the machine radiation source is registered with the appropriate State government, if applicable.

(iii) Documentation that a worker safety program addressing OSHA regulations (29 CFR chapter XVII) is in place.

(iv) Citations or other documents that relate to incidences in which the establishment was found not to comply with Federal or State agency requirements for irradiation facilities.

(v) A certification by the operator that the irradiation facility personnel will only operate under supervision of a person who has successfully completed a course of instruction for operators of food irradiation facilities.

(vi) A certification by the operator that the key irradiation personnel, who monitor or control daily operations, have been trained in food technology, irradiation processing, and radiation health and safety.

(vii) Guarantees from the suppliers of all food-contact packaging materials that may be subject to irradiation, that those materials comply with the Federal, Food, Drug, and Cosmetic Act (21 U.S.C.301 et seq.).”

2. How do I verify compliance?

Under the plant profile:

The first time you enter an establishment that is using irradiation, review all required certificates and documentation to verify that the establishment and all operators have met regulatory requirements to operate.

After the initial review of records, check renewable records such as licenses, periodically to verify that they are current.

IX. LABELING

1. What are the regulatory requirements for labeling?

Section 424.22 (c)(4) states:

“(4) Labeling.

(i) The labels on packages of meat food and poultry products irradiated in their entirety, in conformance with this section and with 21 CFR 179.26(a) and (b), must bear the logo shown at the end of this paragraph (c)(4)(i). Unless the word “Irradiated” is part of the product name, labels also must bear a statement such as “Treated with radiation” or “Treated by irradiation.” The logo must be placed in conjunction with the required statement, if the statement is used. The statement is not required to be more prominent than the declaration of ingredients required under 317.2(c)(2). Any label bearing the logo or any wording of explanation with respect to this logo must be approved as required by Section 317.4 of this chapter or subparts M and N of part 381.

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(ii) For meat food or poultry products that have been irradiated in their entirety, but are not sold in packages, the required logo must be displayed to the purchaser with either the labeling of the bulk container plainly in view or a counter sign, card, or other appropriate device bearing the information that the product has been treated with radiation. In either case, the information must be prominently and conspicuously displayed to purchasers. Unless the word “Irradiated” is part of the product name, the labeling counter sign, card, or other device also must bear a statement such as “Treated with radiation” or “Treated by irradiation.” The logo must be placed in conjunction with the required statement, if the statement is used.

(iii) The inclusion of an irradiated meat food product ingredient in any multi-ingredient meat food or poultry product must be reflected in the ingredient statement on the finished product labeling.

(iv) Optional labeling statements about the purpose for radiation processing may be included on the product label in addition to the stated requirements elsewhere in this section, provided that such statements are not false or misleading. Statements that there has been a specific reduction in microbial pathogens must be substantiated by processing documentation.”

2. How do I verify compliance?

Using ISP code 04B04, review records or observe labels to verify that the establishment has met the regulatory requirements and that the labels comply with the regulations.

a. MEAT FOOD AND POULTRY PRODUCTS IRRADIATED IN THEIR ENTIRETY

Check the product label to see if the required logo is present. If the product name does not include “irradiated,” check to see if a statement such as “treated with radiation” or “treated by irradiation” is present and is placed in conjunction with the logo. Review records to verify that the Labeling Review Branch approved the label.

b. MEAT FOOD AND POULTRY PRODUCTS IRRADIATED IN THEIR ENTIRETY BUT NOT SOLD IN PACKAGES

Verify that the logo is displayed to the purchaser by way of the label on the bulk container or another appropriate device showing that the product has been treated with radiation. If the product name does not include “irradiated” check to see if statement such as “treated with radiation” or “treated by irradiation” is present.

c. MULTI-INGREDIENT MEAT FOOD AND POULTRY PRODUCTS CONTAINING IRRADIATED PRODUCT

Verify that the irradiated product is listed as being irradiated, (e.g., irradiated beef), in the ingredient statement. **Note:** The logo does not need to be on the label nor does any other type of statement.

d. OPTIONAL LABELING STATEMENTS REGARDING REDUCTION IN MICROBIAL PATHOGENS

Review documentation to verify that the Labeling Review Branch has approved the claim. Verify that the claim being made has been validated in the product’s HACCP plan.

3. Can an establishment ship product that already has been packaged and labeled to an irradiation facility for treatment?

Yes. FSIS expects both the shipping and receiving establishment to have controls in place to ensure that all product labeled as irradiated receive the irradiation treatment. Inspection program personnel should verify the establishment's controls.

4. What are the requirements for an establishment that irradiates raw, non-intact beef product known to contain *E. coli* O157:H7?

Irradiators of product must address the elimination of *E. coli* O157:H7 in raw non-intact beef products in their HACCP plan.

X. TRAINING

What type of training will inspection program employees receive?

Inspection program personnel will receive training such as Radiation Fundamentals, Radiation Exposure, Radiation Protection, and Personnel Dosimetry.

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Who will provide the training?

The USDA Radiation Safety Staff (RSS) in coordination with FSIS will provide training.

XI. INSPECTION PERSONNEL SAFETY

Are you required to wear dosimetry badges?

Yes. Inspection program employees are required to wear individual dosimetry badges when working in an irradiation facility to record any occupational dosage received.

Where do inspection program employees receive the personal dosimetry badge?

The USDA RSS supplies thermoluminescent dosimetry badges to FSIS through a private contractor. The FSIS field safety and health specialists will initiate badge service when requested by their assigned District Office (DO). At the end of each monitoring period all badges should be returned to the DO so they can be given to the RSS contractor.

Who maintains inspection program employee exposure records?

RSS keeps radiation exposure records for inspection program employees.

XII. ENFORCEMENT ACTIONS

Establishment addressing irradiation in its HACCP plan

If an establishment has not complied with the irradiation provisions in 9 CFR 424.22, you will follow the instructions found in FSIS Directive 5000.1, Part Two, Paragraph III, C. Use the appropriate 03 ISP code when you document noncompliance on the FSIS Form 5400-5, Noncompliance Record.

Establishments not addressing irradiation in its HACCP plan

If an establishment has not complied with the irradiation provisions in 9 CFR 424.22, you will follow the instructions found in FSIS Directive 5400.5, Part Two, Paragraph III, C. Use ISP code 04B04 when you document noncompliance on the FSIS Form 5400-5, Noncompliance Record.

All establishments

If an establishment has not complied with the labeling provisions in 9 CFR 317.14 or 381.135, document the noncompliance on a NR under ISP activity code 04B04.

XIII. GUIDANCE

For technical guidance contact the Technical Service Center. For guidance related to regulatory activities refer questions through supervisory channels.

/s/ Philip S. Derfler

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